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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,628	11/13/2001	Ronald L. Ream	112703-203	4209

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BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER

HOWARD, SHARON LEE

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,628

Applicant(s)

REAM ET AL.

Examiner

Sharon L. Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Receipt of the response to the office action and the remarks filed on 3/24/05 have been acknowledged. Claims 9-26 remain pending in this application.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (USP 5,665,406) in view of Khan et al. (USP 5,656,296).

Reed teaches a pellet chewing gum which is coated with one or more coats of a polyol such as maltitol, lactitol and erythritol. Reed teaches that the chewing gum includes a gum center and an outer coating. Reed teaches that the gum center constitutes from about 35 to about 90 weight percent of the chewing gum product. The gum center which is sugarless comprises xylitol, maltitol and/or sorbitol. The outer coating contains from about 50 to about 100 weight percent of two polyols. See the abstract and see col.5, lines 5-25. Reed also teaches that the coating may also contain

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from about 0.05 to about 0.3 weight percent of artificial sweeteners such as aspartame, acesulfame-K, saccharin and suralose. See col.7, lines 52-55 and col.8, lines 1-6. The gum base contains from about 10 to about 50% by weight of the chewing gum center. See col.8, lines 50-59. The reference clearly shows a chewing gum pellet which is coated with a polyol, having a sugarless gum center.

Reed does not teach the particular medicament.

However, Khan teaches drug delivery systems containing a core which comprises a medicament, including a waxy material and a coating layer over the core. See col.2, lines 46-51. Khan teaches medicaments such as analgesics, anti-inflammatory agents, cardiovascular preparations, decongestants and vitamins and minerals. See col.3, lines 24-51. Khan teaches that the coating layer of the drug delivery system may also contain sweetening agents and active agents. See col.7, lines 1-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular medicament taught by Khan in the Reed reference, for the purpose of delivering medicaments to the outer layer.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,298,263 teaches that the ingredient isomaltulose is a medicament.

Response to Arguments

Applicant's arguments filed 3/24/05 have been fully considered but they are not persuasive. Applicant argues that there is no suggestion or motivation to combine the

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cited references to obtain the claimed invention, and even if combinable, all of the claimed elements are not taught or suggested by the cited references. There is no suggestion or motivation to combine the cited references to obtain the claimed invention. There is no direction provided in the cited references suggesting how they should be combined to obtain the claimed invention. Indeed, Applicants respectfully submit that it is only with an improper hindsight reconstruction of Applicant's claimed invention that the Patent Office is able to attempt to piece together a rejection of the claims. Applicants also respectfully submit that, even if combinable, the cited references do not disclose all of the claimed elements. For instance, *Reed* fails to disclose a medicament in the coating or even any medicament anywhere in the product. *Khan* fails to remedy the deficiencies of *Reed*. Contrary to the present claims, *Khan* fails to disclose or suggest a medicament in the coating. Indeed, *Khan* teaches away from this concept. Nowhere in the specification does *Khan* specifically disclose or suggest a medicament in the coating. In contrast, the present invention places the medicament within the coating, which is the exact opposite concept of *Khan*. Although the Patent Office alleges that *Khan* teaches that the coating layer of the drug delivery system may also contain sweetening agents and active agents, these ingredients are not medicaments. One having ordinary skill in the art would not consider the inert ingredients as medicaments. Further, *Khan* clearly distinguishes its medicaments by listing them. Thus, if anything, *Khan* can be said to teach away from the claimed invention. For the reasons discussed above, the combination of *Reed* in view of *Khan* does not teach, suggest, or even disclose the claimed invention, and thus, fails to

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render the claimed subject matter obvious for at least these reasons. Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 8-26 be reconsidered and the rejections be withdrawn.

In response to the arguments, Reed ('406) does teach coating a chewing gum with an active agent such as hydrogenated isomaltulose (see col.6, lines 54-61). There is motivation for combining the references since both Reed and Khan teach coating an active agent or a drug. Thus, the claims ~~does~~ render applicant's claims obvious.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon Howard
June 8, 2005



THURMAN K. PAGE
SUPERVISOR
TECHNICAL CENTER 1600
PATENT EXAMINER